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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/905,083 | 07/13/2001 | Timothy I. O'Brien | D6223CIP/C/D | 4623 |

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| EXAMINER | |
|---|---|
| MYERS, CARLA J | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1634 | |

DATE MAILED: 06/13/2002

05

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. 09/905,083 | Applicant(s) O'BRIEN, TIMOTHY I. | |
|---|---|---|---|
| | Examiner Carla Myers | Art Unit 1634 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) 5-10 and 16-39 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 5-10 and 16-39 are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

## *RESTRICTION*

1. Restriction to one of the following inventions is required under 35 U.S.C. § 121:

I. Claims 5-10, drawn to methods for detecting malignant hyperplasia by assaying for mRNAs encoding for SSCE, classified in Class 435, subclass 6.

II. Claims 16, 37, and 38, drawn to antisense therapeutic methods, classified in Class 514, subclass 44.

III. Claims 17-21, drawn to methods of inhibiting expression using an antibody, classified in Class 424, subclass 138.1.

IV. Claims 18-21, drawn to methods of inhibiting expression using a ligand, classified in Class 514, subclass 2.

V. Claims 22-31, drawn to methods of vaccination, classified in Class 424, subclass 184.1.

VI. Claims 32-34, drawn to immunogenic compositions, classified in Class 530, subclass 300.

VII. Claims 35 and 36, drawn to oligonucleotides, classified in Class 536, subclass 23.2.

VIII. Claim 39, drawn to a method of screening for inhibitors, classified in Class 435, subclass 4.

2. The inventions are distinct, each from the other because of the following reasons:

Inventions I-V and VIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation,

different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the different inventions are drawn to distinct methods which require performing different method steps and involve the use of different reagents. In particular, the methods of invention I require the use of primers and probes and involve performing PCR or nucleic acid hybridization assays to detect the presence of mRNA as indicative of the occurrence of malignant hyperplasia. Invention II requires the use of a vector comprising antisense oligonucleotides and treatment of an individual or a cell in order to achieve the objective of inhibiting gene expression. Invention III requires the use of an antibody and treatment of an individual or cell with an antibody in order to achieve the objective of inhibiting protein activity. Invention IV requires the use of a ligand and treatment of an individual or cell with a ligand in order to achieve the objective of inhibiting protein activity. Invention V requires the use of a vaccine comprising a protein and administration of a vaccine to an individual to achieve the objective of vaccinating an individual. Invention VIII requires the use of a test compound and SSCE protein and assaying for protease activity in order to achieve the objective of identifying compounds that inhibit hepsin activity. Inventions I-V and VIII are novel and unobvious over each other.

Inventions I and VI, and inventions II and VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not disclosed as capable of use together and have

different functions because the methods of inventions I and II do not require the proteins of invention VI.

Inventions I and VII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the oligonucleotides of invention VII can be used in a materially different process such as for synthesizing polypeptides or for therapeutic purposes.

Inventions II and VII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the oligonucleotides of invention VII can be used in a materially different process such as for synthesizing polypeptides or for diagnostic purposes.

Inventions III and VII, IV and VII, V and VII and VIII and VII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not disclosed as capable of use together and have different functions because the methods of inventions III, IV, V and VIII do not require the oligonucleotides of invention VII.

Inventions III and VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the proteins of invention VI can be used in a materially different process such as for generating antibodies or for diagnostic purposes.

Inventions IV and VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the proteins of invention VI can be used in a materially different process such as for generating antibodies or for diagnostic purposes.

Inventions V and VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the proteins of invention VI can be used in a materially different process such as for diagnostic purposes or for screening for protease inhibitors.

Inventions VIII and VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the

product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the proteins of invention VI can be used in a materially different process such as for generating antibodies or for therapeutic purposes.

Inventions VI and VII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not disclosed as capable of use together and have different functions and effects. In particular, the proteins of invention VI are composed of amino acids whereas the oligonucleotides of invention VII are composed of nucleotides. Proteins and nucleic acids have distinct structural and physicochemical properties and are utilized in distinct methodologies, such that proteins may be utilized in ligand binding assays and oligonucleotides may be utilized in nucleic acid hybridization assays. The oligonucleotides of invention VII are not required to obtain the proteins of invention VI because the proteins may be chemically synthesized or isolated from natural sources.

Because these inventions are distinct for the reasons given above and have acquired a different status in the art as demonstrated by their different classification and recognized divergent subject matter and because inventions I-VIII require different searches that are not co-extensive, examination of these distinct inventions would pose a serious burden on the examiner and therefore restriction for examination purposes as indicated is proper.

3. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carla Myers whose telephone number is (703) 308-2199. The examiner can normally be reached on Monday-Thursday from 6:30 AM-5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones, can be reached on (703)-308-1152. The fax number for the Technology Center is (703)-305-3014 or (703)-305-4242.

Any inquiry of a general nature or relating to the status of this application should be directed to the receptionist whose telephone number is (703) 308-0196.

Carla Myers

June 10, 2002

CARLA J. MYERS
PRIMARY EXAMINER